

Economic Impact Statement

LSA Document #14-199

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

The Board of Animal Health (BOAH) is requesting approval to amend its rules governing dairy products inspection ([345 IAC 8](#)). The primary purpose of the changes is to conform BOAH rules to the 2013 Grade A Pasteurized Milk Ordinance (PMO). BOAH is proposing to update the current incorporation by reference of the 2011 PMO to the 2013 revision. BOAH is also proposing to update the current incorporation by reference of certain Food and Drug Administration (FDA) food standards from April 1, 2012, to April 1, 2014. The proposed rule will conform BOAH dairy rules to changes in the state dairy inspection law made in the 2014 session of the General Assembly, including the rule governing penalties for drug residue violations. The proposed rule will amend [345 IAC 8](#) to clarify milk testing standards, remove certain raw milk sediment testing requirements, and make other updates and amendments to the dairy inspection rules.

1. Description of Affected Industry

As stated above, the proposed rule updates existing dairy product rules to align with federal standards for Grade A products, which include milk products such as cottage cheese, fluid milk, and yogurt. These types of dairy products are regulated by the FDA under the PMO. Indiana currently has 1,192 Grade A farms and 25 Grade A plants operating in the state.

The state's Grade A plants and farms rely on the BOAH to adopt and enforce the most current version of the PMO. If the board does not incorporate the most recent version of the federal standards, it could jeopardize their ability to ship their product in interstate commerce. This could occur due to a plant or farm failing their FDA survey, which occurs every two years. A failed survey could result in a plant or a Bulk Tank Unit (BTU), which is comprised of several farms, being delisted from the interstate shippers list. A delisting prohibits a plant or BTU from shipping their milk across state lines. Alternatively, this could occur due to Indiana ultimately failing the FDA check rating process, which would jeopardize the ability for all plants and farms to access out of state markets for their products.

The proposed rule also clarifies existing dairy products rules for manufacturing grade dairy products, such as cheese and ice cream. The standards for these types of dairy products are established by each state. Indiana currently has 101 manufacturing grade farms and 26 plants operating in the state.

According to the most recent survey conducted by the National Agricultural Statistics Service (NASS), the estimated value of the Indiana dairy industry in 2013 was 791 million dollars annually.¹ The dairy industry in Indiana ships approximately 3,888 million pounds of product in intrastate and interstate commerce annually.² This is a considerable amount of private investment at increased risk if BOAH does not have the most current standards in place.

BOAH has worked extensively to involve these regulated entities in the development of the rule. For example, the proposed changes were presented to the Indiana Dairy Producers Association, Indiana milk marketing associations, dairy processing plants, and other interested stakeholders at the June 2014 BOAH Dairy Industry Meeting. BOAH has made amendments to the rule in response to feedback received. The affected industry includes small businesses under the definition at [IC 4-22-2.1-4](#).

2. Estimated Annual Reporting, Record Keeping, and Other Administrative Costs

The proposed rule does amend a records retention requirement for dairy processing plants. Specifically, it extends the retention requirement for bacterial testing results from one year to two years. However, this change fully reflects the federal standard in place that governs the interstate shipment of milk. In addition, the BOAH does not anticipate the retention of these records for an additional year to impose a significant administrative cost on the state's processing plants.

3. Estimated Total Annual Economic Impact on Small Businesses

This rule does not increase compliance costs for regulated entities. Rather, by amending current requirements, it has the potential to lower compliance costs for permit holders. For example, it extends the time allowed for a laboratory analysis to begin on a raw milk sample from 48 hours to 60 hours to align with federal standards. It allows raw sheep and goat milk to be stored on a dairy farm for up to seven days, which is an extension from the two day requirement for cow's milk. It also removes outdated sediment testing standards. It allows manufacturing grade processing plants to store certain dry ingredients on wood flooring. All of these changes provide permit holders more flexibility in how they operate, which presents opportunities for cost savings.

It is also important to note that the proposed rule reduces the civil penalties for drug residue violations to align with the PMO and statutory changes in the 2014 session of the General Assembly. The rule allows the agency to reduce the penalty for a second or third violation by the amount the producer had to reimburse the

cooperative for contaminating other producers' milk. It also no longer mandates that the agency revoke the producer's permit for 30 days following a third violation within a 12 month period. Drug residue violations are a rare occurrence in the dairy industry. However, these changes will provide cost savings for regulated entities because the agency is not required to impose an unduly burdensome fine on a producer that is working in good faith to correct a residue issue in their herd.

It is important to note that the proposed rule does reduce the acceptable amount of sediment in milk. However, this change fully reflects federal standards in place that govern the interstate shipment of milk. The proposed rule also provides more detail regarding what is considered a "separate milking area" for a manufacturing grade farm. However, this is merely a clarification of an existing standard. The proposed rule clarifies that a manufacturing grade processing plant must commingle samples prior to testing for somatic cell count and bacteria, but this is also a clarification of an existing requirement. Although this clarification may entail an adjustment to the process of some plants, the BOAH does not anticipate that ensuring the milk is commingled prior to sampling will impose a significant additional cost.

4. Justification of Requirements

a. Compliance with Federal Law

The proposed rule is necessary to comply with a federal mandate. BOAH is a voting member of the NCIMS. As a member of this entity, each state has agreed to enforce the sanitation standards set forth in the PMO. The FDA audits state program implementation by conducting check ratings. The check rating process involves the FDA inspecting all farms and plants in Indiana every six years. If BOAH does not update the incorporation by reference, Indiana would not be able to enforce the most current federal requirements to ship milk in interstate commerce. Therefore, Indiana would be in violation of its agreement with FDA.

b. Compliance with State Law

This proposed rule is necessary to comply with a state mandate. State law requires the board to adopt rules that are the same as, or at least as effective in protecting health, as the federal standards for Grade A milk adopted by the National Conference on Interstate Milk Shipments (NCIMS) in accordance with their Memorandum of Understanding (MOU) with the FDA. [IC 15-18-1-14](#). The PMO is the document that is accepted by the FDA as the federal standards for the interstate shipment of milk. Therefore, in order to comply with this statutory mandate, the agency must ensure that the most recent revision of the PMO is being referenced in the state dairy products rule.

c. Justification of Intrastate Requirements Not Mandated by Federal Law

As discussed above, the proposed rule provides more detail regarding what it considered a "separate milking area" for a manufacturing grade farm. It also clarifies that a manufacturing plant must commingle samples prior to testing for somatic cell count and bacteria. However, because these changes are merely clarification of existing requirements, the proposed rule does not impose a requirement or cost beyond what is expressly required by state or federal law.

5. Regulatory Flexibility Analysis

Because the proposed rule does not impose requirements above the federal standards, BOAH did not examine alternative methods with regard to Grade A dairy products standards. However, BOAH did consider less costly alternative methods to achieving the purpose of the proposed rule with regard to manufacturing grade milk products. As stated above, the proposed rule clarifies the "separate milking area" and milk sample testing requirement for manufacturing grade farms. After involving regulated entities, BOAH made a determination that adding more detail to the rule itself was preferable to the alternative of issuing a guidance document.

One reason for this determination was to simplify compliance through consolidation of requirements. With regard to the stringency of the standards, both of the requirements align with other states and serve a critical public health purpose of ensuring that raw milk for processing does not contain unsafe levels of bacteria. Therefore, the BOAH made a determination that the agency should not establish less stringent standards with regard to these activities. It is also important to note that these are performance standards which allow plants flexibility to adapt their design and operation to achieve compliance in a way that best suits their needs.

¹ National Agriculture Statistics Service - 2013 Indiana Survey
<http://quickstats.nass.usda.gov/data/printable/9EC6522D-46F1-3C00-865C-3725AAAA5F1E>

² National Agriculture Statistics Service - 2013 Indiana Survey
<http://quickstats.nass.usda.gov/data/printable/D91A3D9F-9756-3108-B4D1-95B4B14C99B1>